CLAIMS

1. A pharmaceutical composition in a form of an anhydrous self-nanoemulsifying oily formulation comprising:

- one or more therapeutic agent(s) which have low solubility in water or are water-insoluble,
- vitamin E,
- one co-solvent selected from propylene glycol and ethanol and mixture thereof
- one surfactant selected from tyloxapol and from mixture of tyloxapol and TPGS, and optionally,
- a bioenhancer.

2. A pharmaceutical composition according to claim 1 further comprising an acidic pH adjuster.

3. A pharmaceutical composition according to anyone of claims 1 to 2, wherein vitamin E is from 2 to 6% (w/w) of the final composition.

4. A pharmaceutical composition according to anyone of claims 1 to 3, wherein the one or more therapeutic agent(s) is selected from the group comprising anti-fungal drugs, anti-viral drugs, antibiotic drugs, anti-inflammatory drugs, anti-cancer drugs, analgesics, antidepressants, antipsychotics, hormones, antacids, coronary vasodilators, cerebral vasodilators, psychotropics, antineoplastics, stimulants, anti-histamines, vasodilators, anti-arrythmics, anti-hypertensive drugs, vasoconstrictors, anti-migraine drugs, anti-coagulants and anti-thrombotic drugs, anti-pyretics, hypnotics, sedatives, anticonvulsants, anti-epileptics, neuromuscular drugs, drugs acting on Central Nervous System, hyper- and hypoglycemic agents, diuretics, anti-obesity drugs, anabolic drugs, anti-uricemic drugs, immunosuppressant drugs and combinations thereof.

5. A pharmaceutical composition according to anyone of claims 1 to 4, wherein the one or more therapeutic agent(s) is selected from the group comprising anti-cancer drugs, antineoplastic drugs and combinations thereof.

6. A pharmaceutical composition according to anyone of claims 1 to 5, wherein the anti-cancer drug is a taxoid, preferably selected from paclitaxel, docetaxel, their derivatives, analogs and prodrugs.

7. A pharmaceutical composition according to anyone of claims 1 to 6, wherein the taxoid is paclitaxel in a relative proportion between 0.5 and 4% (w/w) of the final composition, preferably between 1.5 and 3% (w/w).

8. A pharmaceutical composition according to anyone of claims 1 to 7, wherein the relative proportions of vitamin E, TPGS and tyloxapol are respectively 2-6, 0-60 and 5-70 (w/w) of the final composition, preferably respectively 2-6, 5-60 and 5-70 (w/w) of the final composition, more preferably respectively 3-5, 20-40 and 20-40%.

9. A pharmaceutical composition according to anyone of claim 1 to 8 wherein the relative proportion of propylene glycol is in the range of 0-50% (w/w) of the final composition, preferably equal to 20% (w/w) and the relative proportion of ethanol is in the range of 5-50% (w/w) of the final composition, preferably equal to 30% (w/w).

10. A pharmaceutical composition according to anyone of claims 1 to 9, wherein the enhancer is selected from the group comprising cytochrome P450 2C8 inhibitors, cytochrome P450 3A4 inhibitors, multidrug resistance inhibitors, Pgp inhibitors or non specific inhibitors.

11. A pharmaceutical composition according to claim 10, wherein the enhancer is cyclosporine A, its analogs and derivatives.

12. A pharmaceutical composition according to anyone of claims 2 to 11, wherein the acidic pH adjuster is anhydrous citric acid.

13. A pharmaceutical dosage form comprising an anhydrous self-nanoemulsifying oily formulation composition according to anyone of claims 1 to 12 associated to suitable pharmaceutical excipients.

14. A pharmaceutical dosage form according to claim 13, which is suitable for the oral route.

15. A pharmaceutical dosage form according to claim 14 wherein the composition is encapsulated in a soft or hard gelatin capsule or is a liquid oily preparation.

16. A pharmaceutical dosage form according to claim 13, which is suitable for the intravenous route.

17. Use of an anhydrous self-nanoemulsifying oily formulation according to anyone of claims 1 to 12 for the manufacture of a medicament useful in the treatment of taxoid-responsive diseases.

18. Use according to claim 17 for administration to patients receiving simultaneously with, concomitantly or prior to, bioavailability enhancing agent and/or another antitumor agent.

19. Use of an anhydrous self-nanoemulsifying oily formulation according to anyone of claims 1 to 12 for the manufacture of a medicament wherein the dose of the therapeutic agent administered is linearly proportional to the blood plasma level of the therapeutic agent desired.

20. Use of tyloxapol and of mixture of tyloxapol and TPGS, for preparing pharmaceutical composition in the form of anhydrous self-nanoemulsifying oily

formulation suitable for preparing a medicament wherein the dose of the therapeutic agent administered is linearly proportional to the blood plasma level of the therapeutic agent desired.

21. Method of treatment of taxoïd-responsive diseases wherein an effective amount of a composition according to claim 1 is administered to a patient in the need thereof.